

<b>Notice of Allowability</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/723,197	RODGERS ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Chih-Min Kam	1653	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 11/14/03.
2. ☒ The allowed claim(s) is/are 1,9,10,14 and 20-47.
3. ☐ The drawings filed on \_\_\_\_\_ are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All    b) ☐ Some\*    c) ☐ None    of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
  6. ☒ CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
    - (a) ☒ including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
      - 1) ☐ hereto or 2) ☒ to Paper No./Mail Date 7/26/02.
    - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

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|---|---|
| <ol style="list-style-type: none"> <li>1. <input type="checkbox"/> Notice of References Cited (PTO-892)</li> <li>2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)</li> <li>3. <input checked="" type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),<br/>Paper No./Mail Date <u>9/25/03</u></li> <li>4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit<br/>of Biological Material</li> </ol> | <ol style="list-style-type: none"> <li>5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)</li> <li>6. <input checked="" type="checkbox"/> Interview Summary (PTO-413),<br/>Paper No./Mail Date <u>0204</u></li> <li>7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment</li> <li>8. <input type="checkbox"/> Examiner's Statement of Reasons for Allowance</li> <li>9. <input type="checkbox"/> Other _____</li> </ol> |
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 CHRISTOPHER S. F. LOW  
 SUPERVISORY PATENT EXAMINER  
 TECHNOLOGY CENTER 1600

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An **Examiner's Amendment** to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with David Harper on February 18, 2004.

**Examiner's Amendments to the Specification:**

Please replace the first paragraph at page 1, lines 5-11 with the following paragraph:

This application claims priority to U. S. Provisional Patent Application Nos: 60/201,470 filed May 3, 2000; 60/220,804 filed July 25, 2000; 60/233,375 filed September 18, 2000; 60/235,040 filed September 25, 2000; and 60/243,955 filed October 27, 2000; and is a Continuation-In-Part of U. S. Patent Application Serial No. 09/307,940 filed May 10, 1999, which claims the priority of U. S. Provisional Application Nos: 60/092,633 filed July 13, 1998 and 60/084,908 filed May 11, 1998. This Application is related to co-pending and commonly owned patent applications 09/012,400 filed January 23, 1998; 09/564,051 filed May 3, 2000; 09/564,045 filed May 3, 2000; 09/264,563 filed March 8, 2000; 09/245,680 filed February 8, 1999; and 09/658,315 filed September 8, 2000.

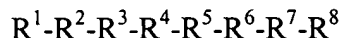
**Examiner's Amendments to the Claims:**

Claims 1, 28 and 31 have been amended as follows:

1. (Currently amended) An improved method for chemotherapy in a human patient, wherein the improvement comprises administering to the human chemotherapy patient an amount of at least one active agent effective [for treating or reducing] to treat chemotherapy side effects, or to reduce the frequency,

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[and/or] severity, or the frequency and severity of chemotherapy side effects, [of at least one] wherein the active agent [comprising] comprises a sequence consisting of at least five contiguous amino acids of groups  $R^1$ - $R^8$  in the sequence of general formula I



Wherein  $R^1$  is Asp[,];

$R^2$  is Arg;

$R^3$  is Val;

$R^4$  is Tyr;

$R^5$  is Ile;

$R^6$  is His;

$R^7$  is Pro; and

$R^8$  is Phe or is absent,

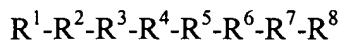
excluding sequences including  $R^4$  as an N-terminal Tyr group;

and wherein the active agent is not SEQ ID NO:1,

wherein the chemotherapy side effects are selected from the group consisting of hematopoietic toxicity, decreased mobilization of hematopoietic progenitor cells from bone marrow into the peripheral blood[,], anemia, myelosuppression, pancytopenia, thrombocytopenia, neutropenia, lymphopenia, leukopenia, stomatitis, alopecia, headache, and muscle pain; and wherein said administering is for a time and under conditions effective to reduce the frequency, severity, or the frequency and severity of chemotherapy side effects.

28. (Currently amended) A pharmaceutical composition comprising

a) an [amount of] active agent comprising a sequence consisting of at least five contiguous amino acids of groups  $R^1$ - $R^8$  in the sequence of general formula I



Wherein  $R^1$  is Asp;

$R^2$  is Arg;

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R<sup>3</sup> is Val;R<sup>4</sup> is Tyr;R<sup>5</sup> is Ile;R<sup>6</sup> is His;R<sup>7</sup> is Pro; andR<sup>8</sup> is Phe or is absent,excluding sequences including R<sup>4</sup> as an N-terminal Tyr group;and wherein the active agent is not SEQ ID NO:1,

in an amount sufficient to provide a dosage to a patient of between 2.5 µg/kg/day and 100 µg/kg/day, and effective to treat chemotherapy side effects, or to reduce the frequency, severity, or the frequency and severity of chemotherapy side effects; and

b) a pharmaceutically acceptable carrier.

31. (Currently amended) The pharmaceutical composition of claim 30 wherein the cytokine is selected from the group consisting of granulocyte colony stimulating factor, granulocyte-macrophage-colony stimulating factor (GM-CSF), epidermal growth factor, interleukin 11, thrombopoietin, megakaryocyte development and growth factor, pixykinases, stem cell factor, FLT (*fms*-like tyrosine kinase)-ligand, and interleukins 1, 3, 6, and 7.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571) 272-0951. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 308-4227 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Chih-Min Kam, Ph. D. *CMK*  
Patent Examiner

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February 18, 2004

*Christopher S. F. Low*  
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SUPERVISORY PATENT EXAMINER  
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